

## Vaccine testing: can we reduce fish numbers and/or avoid fish use?

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The development and documentation of effective vaccines for farmed fish has during the last decades increased substantially as the aquaculture sector worldwide has been industrialized. Vaccines for farmed fish have been a remarkable successes in disease prevention and there is a significant increase in vaccination against bacterial and viral pathogens in the worldwide aquaculture industry.

The use of laboratory animals during the development, registration and batch release of fish vaccines are regulated by national and European legislation (Guidelines and Monographs). Currently, the regulatory requirements determine the level of maneuverability that pharmaceutical companies have in order to minimizing the use of laboratory animals when documenting the efficacy of fish vaccines, or to confirm the potency/safety of production batch prior to commercial release.

As *in vivo* methods are still necessary for evaluation of existing and new vaccines for fish, a consequence of this is an that an increase in the number of laboratory animals (fish) used during development, licensing and quality control of fish vaccines has arisen.

Pharmaceutical companies developing vaccines for fish rely on *in vivo* vaccination / challenge trials in order to develop efficacious and safe vaccines for commercial fish farming and replacement of these trials by *in vitro* models does not seem realistic at the moment. However, as the highest number of laboratory animals is being used during quality control of fish vaccines prior to batch release, the replacement of *in vivo* with *in vitro* tests during this stage therefore has the greatest potential to reduce the numbers of laboratory animals used in laboratory trials. As fish vaccines are manufactured under the GMP “umbrella” for safety and efficacy, tests could be omitted if consistency of production has been documented and demonstrated (currently all commercial production batches have to be tested prior to release). During the final stages of the development of a fish vaccine, large scale commercial field trials are required in order to document the efficacy and safety of the product. Today, a field trials in Norway with Atlantic salmon may include 2-4 million individual fish, and as these fish are ordinary production fish of the farm, a discussion related to the definition of these animals should be initiated.